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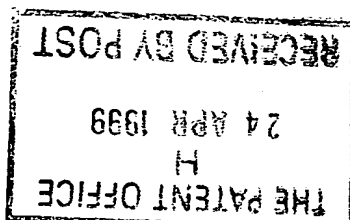
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CGP / 1G3694

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9909357.7

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UNITED KINGDOM

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

MEDICAMENT CARRIER

5. Name of your agent (if you have one)

DR CHRISTOPHER G PIKE

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

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3 KILDAYKE

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DR CG PIKE - AGENT FOR THE APPLICANT

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Medicament Carrier

The present invention relates to a medicament carrier for incorporation into an inhalation device to enable administration of medicament to a patient.

5

Inhalation devices are known for use with blister packs in which the medicament is held in powder form in the blisters thereof. Such packs are typically comprised of two separate entities, one of which is suitably formed to define the medicament pocket and the other is hermetically sealed to the first to form the medicament
10 carrier. It is an object of the present invention to provide a medicament carrier wherein the carrier comprises a single elongate strip thus providing significant advantages over the prior art in that the strip is straightforward to manufacture, providing both ease of use and reduction in manufacturing costs.

15 Known blister packs generally include a puncturing member, which punctures each blister in turn thus enabling the medicament to be inhaled therefrom. Generally release of the medicament dose is by puncture or rupture of the second entity. Such packs suffer from the disadvantage that they may be difficult to use, particularly as the dose releasing means may comprise one or more elongate
20 members, such as cords or tapes, which are separately attached to films used to seal the medicament pockets. The present invention in embodiments provides advantages over such packs in that it is especially useful for the elderly and infirm since the free end of the strip is readily identifiable and simple to grasp, without the added complication of numerous cords or tapes which act as a separate release
25 mechanism.

It will also be seen that in several embodiments of the present invention the free end of the strip is peeled back automatically by virtue of a releasing means incorporated into the inhalation device, hence avoiding the need to grasp the strip manually.
30 Such a feature further enhances the ease of use of the inhalation device since minimum force is required by the user to peel back the medicament pocket.

It is also an object of the present invention to provide a medicament carrier for use in combination with an inhalation device, wherein the design of the inhalation device
35 has the potential, if desired, to handle a medicament carrier having a large number of discrete unit doses without the device becoming unacceptably large. Thus, although a single use inhaler is referred to in the drawings/illustrations, it is possible

that such an inhaler may be easily adapted to accommodate a multi-dose medicament container.

According to one aspect of the invention there is provided a medicament carrier
5 comprising an elongate strip having a first portion and a second portion; a pocket in said first portion for containment of medicament; a fold in said second portion such that the second portion is foldable towards said pocket to form a cover therefor; and a seal between said cover and the pocket.

10 In another aspect of the invention there is provided a medicament carrier comprising a plurality of pockets in the first portion, wherein the second portion is foldable towards said plurality of pockets to form a cover therefor.

In another aspect of the invention there is provided a medicament carrier comprising
15 a second fold in the second portion to form a pull release tab.

Preferably, the pull release tab is shaped for ease of grip.

Preferably, the pull release tab has a looped end enabling it to be connected to a
20 trigger mechanism incorporated within an inhalation device or for receipt of finger in manual release.

Preferably, the pull release tab has at least one perforation therein allowing it to be easily grasped by the user or otherwise allowing it to be connected to a trigger
25 mechanism incorporated within an inhalation device.

In another aspect of the invention there is provided a medicament carrier in multi-dose form comprising a series arrangement of a plurality of medicament carriers as described above.

30 Preferably, each of said plurality of medicament carriers is connected-together.

More preferably, each of said plurality of medicament carriers is formable from the same elongate strip.

35 Preferably, the elongate strip has a point of weakness between each medicament carrier in said series arrangement; thereby enabling separation of individual medicament carriers from the strip.

Preferably, the elongate strip is flexible to enable it to be formed for example, into a spiral, helical or zig-zag shape for incorporation into a suitable inhalation device. More preferably, the elongate strip is made of an elastic material, for example
5 flexible foils or plastic materials.

Preferably, the seal is formable by a sealing method selected from the group consisting of heat, laser, radio frequency, adhesive, staple, stamp and ultrasonic sealing.

10

Preferably, the seal is peelable to enable peelable access to the pocket.

Preferably, the pocket is shaped for receipt by a holder.

15 Preferably, the pocket comprises medicament in powder form.

In a further aspect of the present invention there is provided an inhalation device comprising a housing in combination with a medicament carrier.

20 Preferably, the housing includes a holder for receipt of the pocket of the medicament carrier.

Preferably, the medicament carrier comprises a pull release tab and the pull release tab protrudes from the housing.

25

Preferably, the inhalation device comprises a release trigger and the pull release tab connects to the release trigger. More preferably, the release trigger is separable from the housing.

30 According to another aspect of the present invention there is provided a method of making a medicament carrier comprising forming a pocket in a first portion of an elongate strip; filling said pocket with medicament; folding a second portion of said elongate strip towards the pocket to form a cover therefor; and forming a seal between said cover and the pocket.

35

Preferably, the method comprises forming a plurality of pockets in a said portion of said elongate strip; filling said plurality of pockets with medicament; folding a second

portion of the elongate strip towards the plurality of pockets to form a cover therefor; and forming a seal between said cover and the plurality of pockets.

In another aspect of the present invention, there is provided a method of making a
5 medicament carrier in multi-dose form comprising successive iterations of the method described hereinbefore to form a series arrangement of a plurality of medicament carriers.

According to another aspect of the present invention there is provided a method of
10 opening a medicament carrier as described herein comprising pulling the pull release tab in order to enable access to the pocket.

According to yet another aspect of the invention there is provided the use of a medicament carrier as described herein for dispensing medicament.

15

Preferably, the medicament is used in the treatment of respiratory disorders.

More preferably, the medicament is used in the treatment of asthma.

20 Preferably, the medicament is salbutamol or albuterol.

Preferred embodiments of the medicament carrier according to the present invention will now be described with reference to the accompanying drawings in which:

25 Fig. 1a is a perspective sideview of a first medicament carrier in accordance with the present invention in the closed configuration.

Fig. 1b is a perspective sideview of a first medicament carrier in accordance with the present invention in the open configuration.

30

Fig. 2 is a perspective sideview of a second medicament carrier in a multi-dose form.

Fig. 3a is a perspective sideview of the insert of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1.

35

Fig. 3b is a cross-sectional front view of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1, wherein the mouthpiece is in the closed configuration.

Fig. 3c is a cross-sectional front view of the inhalation device of Figure 3b, wherein the carrier is in the open configuration.

5 Fig. 4a is a perspective view of an inhalation device comprising a medicament carrier in accord with the present invention.

Fig. 4b is a cross-sectional frontview of the insert of an inhalation device incorporating a medicament carrier which is a variation of that shown in Figure 1,
10 wherein the mouthpiece is in the open configuration.

Fig. 5a is a perspective sideview of part of the insert of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1.

15 Fig. 5b is a cross-sectional sideview of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1, wherein the carrier is in the closed configuration.

Fig. 5c is a cross-sectional sideview of the inhalation device of Figure 5b, wherein
20 the carrier is in the open configuration.

Fig. 6a is a cross-sectional sideview of the insert of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1, wherein the carrier is in the closed configuration.

25

Fig. 6b is a cross-sectional sideview of the insert of Figure 6a, wherein the carrier is in the open configuration.

Figure 1a shows a medicament carrier in the closed configuration comprising an
30 elongate strip 10, whose first portion contains a pocket 20 suitable for containing a powdered medicament. A second portion of the elongate strip is folded over once to form a cover for the pocket 20 and folded a second time to define a pull release tab 30. The contents of the pocket 20 are exposed by pulling the pull release tab 30 in a horizontal direction relative to the medicament pocket, either manually or by trigger
35 release mechanism so that the medicament carrier is then in the open configuration as shown in Figure 1b.

Figure 1b shows a medicament carrier in the open configuration wherein the pull release tab 30 has been sufficiently peeled in order to break the seal around the periphery of the pocket 20 thereby removing the cover portion and exposing the medicament contained therein.

5

Figure 2 shows a combination of Figures 1a and b in both the open and closed configurations in which the medicament carrier is in a multi-dose form. The multi-dose medicament carrier is formed from an elongate strip incorporating a number of first portions each containing a medicament pocket 120. A corresponding second
10 portion is folded over once as described above in order to define a cover for said pocket 120 and folded a second time to form a pull release tab 130 with which to break the seal and expose the medicament contained within the pocket.

Figure 3a shows the insert of a first inhalation device designed to accommodate the
15 medicament carrier of the present invention. The insert comprises a separate housing 240 and a flexible ring 250 which slots into said housing. The ring 250 has at least one notch 260 at a suitable point on the circumference. The medicament pocket 220 sits in a retainer 242 within the inhalation device and the looped pull release tab 230 engages with the notch 260 to form a trigger mechanism for
20 releasing the cover of the medicament pocket. Actuation of the trigger mechanism is achieved by the user gripping the ring and pulling it in a downwards motion, whereby the pull release tab 230 is automatically peeled backwards to expose the contents of the pocket 220.

25 Figures 3b and 3c show a first inhalation device comprising the insert described in Figure 3a in the open and closed positions respectively. The medicament carrier of the present invention is housed in a recess 270 and connected to the ring 250 by the pull release tab 230 as described in Figure 3a above. In the storage position (Figure 3b) the circumference of the ring 250 seals the mouthpiece 280 and actuation of the
30 device from this position to the in-use position (Figure 3c) is achieved by a two-handed operation. In practice, this may be achieved by holding the body 290 of the device between thumb and forefinger and pulling the ring 250 in a downward motion as described in Figure 3a. It will be seen that this action causes the pull release tab 230 to be peeled backwards and the contents of the pocket 220 to be exposed.
35 Complete removal of the ring 250 from the body of the device 290 uncovers both the mouthpiece 280 and an airway 295 at the side of the device, enabling the pocket contents to be inhaled through the mouthpiece 280.

Figures 4a and 4b show a second inhalation device comprising a similar insert to that described in Figure 3a. Figure 4a shows an inhalation device wherein the pull release tab 330 protrudes from the housing in order to be freely pulled by the patient. Actuation of the device is similar to that of the device in Figures 3b and 3c. This is achieved by pulling the pull release tab 330 as before (Figure 4a) and rotating a rigid ring 350 (Figure 4b) in order to uncover the mouthpiece 380 and airway 395 to allow the contents of the pocket to be exposed.

Figure 5a shows part of the insert of an inhalation device encompassing a medicament carrier which is a variation of that shown in Figure 1a wherein the looped pull release tab 430 is attached to a notch 460 in the insert to provide a trigger release mechanism.

Figures 5b and 5c show a third inhalation device encompassing a medicament carrier of the present invention in the open and closed configurations, respectively. The device itself comprises a tubular-shaped body 405 with a mouthpiece 415 and a slidably movable projection 425. In the storage position (Figure 5b) the projection 425 is located close to the mouthpiece 415 so that both the mouthpiece and the airway 435 are covered. Actuation of the device from this position to the in-use position (Figure 4c) is achieved by sliding the projection 425 translationally to the forward locked position, which allows air to flow through the airway 435 into a cavity formed 445 and, via the peelable pocket 420, to the mouthpiece 415.

Figures 6a and 6b show a fourth inhalation device incorporating a medicament carrier which is a variation of that in Figure 1a in the open and closed positions, respectively. Figure 6a shows that when the air flows towards the sealing flap 555 in the direction shown, the contact between the sealing flap 555 and the edge of the pocket 520 is not broken. Such airflow would be created by exhalation. When the free end of the strip 530 is pulled to expose the contents of the pocket 520 and the direction of airflow reversed by inhalation, as shown on Figure 6b, then the sealing flap 555 is opened and the medicament present in the medicament pocket 520 is entrained in the airflow and carried through the device to be administered to the patient.

Standard methods of filling and sealing the medicament container may be used and form another aspect of the present invention. Such methods include filling the medicament container by urging the pocket, with its open side downwards, into a reservoir of powder, and withdrawing the pocket therefrom with the quantity of

powder therein and then sealing the container by folding over the elongate strip and providing sealing means so that the powder is contained in a medicament container defined by the pocket and elongate strip. An alternative method comprises entering a hollow, or a number of hollow, pins into a reservoir of powder so that a defined
5 quantity of powder is taken up into the or each pin. The pin, or number of pins, are then positioned above the individual medicament containers and the powder contained therein released by means of a piston. The medicament containers are subsequently sealed as before by folding over the elongate strip and providing sealing means so that the powder is contained in a medicament container defined by
10 the pocket and elongate strip.

In another alternative method the medicament powder may be released from a powder reservoir housed within the inhalation device. For example, a bore is entered into the powder reservoir and the powder transferred through the bore by
15 means of a fluted auger to a bore egress. The medicament powder is then released into a medicament pocket of the desired volume by means of a piston.

Suitable methods of sealing the medicament carrier include the use of adhesives, staples or stamps and welding methods selected from hot metal welding, radio
20 frequency welding, laser welding and ultrasonic welding. Such sealing techniques may be used to form a suitable seal around the periphery of the medicament pocket which is capable of being peeled away by the patient or by a suitable trigger release mechanism in a controlled manner when in use.

25 Although not directly relevant to the present invention, it should be noted that medicaments suitable for administration by an inhalation device using the present invention are any drug particles suitable for delivery to the bronchial or alveolar region of the lung which have an aerodynamic diameter of less than 10 micrometers. Larger particles may be used if delivery to other portions of the respiratory tract is
30 desired, such as the mouth or throat. Such medicaments may be selected from a wide range of powdered medicaments and may be in amorphous or crystalline form and may have been comminuted, e.g. ground, and, if necessary, classified and sieved, e.g. on an air jet sieve, to obtain a suitable size or may have been made by direct crystallisation to the desired size.

35 Appropriate medicaments may thus be selected from those suitable for inhalation, for example, analgesics, e.g. codene, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; anti-allergics, e.g., cromoglycate,

ketotifen or nedocromil; anti-infective e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; anti-histamines e.g., methapyrilene; anti-inflammatories e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone
5 acetonide; anti-tussives, e.g. noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimitrol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- α -[[[6-2-(pyridinyl)ethoxy]hexyl]methyl]benzenemethanol; diuretics, e.g. amiloride;
10 anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon.

15 It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts (e.g. as alkaline metal or amine salts or as acid addition salts) or as esters (e.g. low alkyl esters) or as solvates (e.g. hydrates) to optimise the activity and/or stability of the medicaments.

20 Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and becomethasone dipropionate or solvates thereof, e.g. the sulphate of albuterol and xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations
25 containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g. as in xinafoate salt) in combination with an anti-inflammatory steroid such as beclomethasone ester (e.g., the dipropionate) or fluticasone ester (e.g., the propionate).

30 It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such
35 subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims or may include, by way of example and without limitation, one or more of the following claims:

Claims

- 5 1. A medicament carrier comprising an elongate strip having a first portion and a second portion; a pocket in said first portion for containment of medicament; a fold in said second portion such that the second portion is foldable towards said pocket to form a cover therefor; and a seal between said cover and the pocket.
- 10 2. A medicament carrier according to claim 1 comprising a plurality of pockets in the first portion, wherein the second portion is foldable towards said plurality of pockets to form a cover therefor.
- 15 3. A medicament carrier according to either of claims 1 or 2, comprising a second fold in the second portion to form a pull release tab.
4. A medicament carrier according to claim 3, wherein said pull release tab is shaped for ease of grip.
- 20 5. A medicament carrier according to either of claims 3 or 4, wherein the pull release tab has a looped end.
6. A medicament carrier according to any of claims 3 to 5, wherein said pull release tab has at least one perforation therein.
- 25 7. A medicament carrier in multi-dose form comprising a series arrangement of a plurality of medicament carriers according to any of claims 1 to 6.
- 30 8. A medicament carrier according to claim 7, wherein each of said plurality of medicament carriers is connected together.
9. A medicament carrier according to claim 8, wherein each of said plurality of medicament carriers is formable from the same elongate strip.
- 35 10. A medicament carrier according to claim 9, wherein said elongate strip has a point of weakness between each medicament carrier in said series arrangement.

11. A medicament carrier according to any claims 1 to 10, wherein the elongate strip is flexible.
- 5 12. A medicament carrier according to any of claims 1 to 11, wherein the elongate strip is made of an elastic material.
- 10 13. A medicament carrier according to any one of claims 1 to 12, wherein the seal is formable by a sealing method selected from the group consisting of heat, laser, radio frequency, adhesive, staple, stamp and ultrasonic sealing.
14. A medicament carrier according to any one of claims 1 to 13, wherein the seal is peelable to enable peelable access to the pocket.
- 15 15. A medicament carrier according to any one of claims 1 to 14, wherein the pocket is shaped for receipt by a holder.
- 20 16. A medicament carrier according to any one of claims 1 to 15, wherein the pocket comprises medicament in powder form.
17. An inhalation device comprising a housing in combination with a medicament carrier as claimed in any one of claims 1 to 16.
- 25 18. An inhalation device as claimed in claim 17, wherein the housing includes a holder for receipt of the pocket of the medicament carrier.
- 30 19. An inhalation device according to either of claims 17 or 18, wherein the medicament carrier comprises a pull release tab and the pull release tab protrudes from the housing.
20. An inhalation device according to claim 19, wherein the inhalation device comprises a release trigger and the pull release tab connects to the release trigger.
- 35 21. An inhalation device according to claim 20, wherein the release trigger is separable from the housing.

22. A method of making a medicament carrier comprising forming a pocket in a first portion of an elongate strip; filling said pocket with medicament; folding a second portion of said elongate strip towards the pocket to form a cover therefor; and forming a seal between said cover and the pocket.
- 5
23. A method according to claim 22 comprising forming a plurality of pockets in a said portion of said elongate strip; filling said plurality of pockets with medicament; folding a second portion of the elongate strip towards the plurality of pockets to form a cover therefor; and forming a seal between said cover and the plurality of pockets.
- 10
24. A method of making a medicament carrier in multi-dose form comprising successive iterations of the method according to either of claims 21 or 22 to form a series arrangement of a plurality of medicament carriers.
- 15
25. A method of opening a medicament carrier as claimed in claims 3 to 15 comprising pulling the pull release tab in order to enable access to the pocket.
- 20
26. Use of a medicament carrier, according to claim 16 for dispensing medicament.
27. Use of a carrier according to claim 26, wherein said medicament is used in the treatment of respiratory disorders.
- 25
28. Use of a carrier according to claim 27, wherein said medicament is used in the treatment of asthma.
29. Use of a carrier according to claim 28, wherein said medicament is salbutamol or albuterol.
- 30
30. A medicament carrier as substantially herein described with reference to the accompanying drawings.
31. An inhalation device as substantially herein described with reference to the accompanying drawings.
- 35

Abstract

There is provided a medicament carrier for use in combination with an inhalation
5 device suitable for dispensing medicament, particularly for use in the treatment of
respiratory disorders. The medicament carrier comprises an elongate strip having a
first portion and a second portion; a pocket in said first portion for containment of
medicament; a fold in said second portion such that the second portion is foldable
towards said pocket to form a cover therefor; and a seal between said cover and the
10 pocket. A method of making the medicament carrier is also provided.

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FIGURE 1a

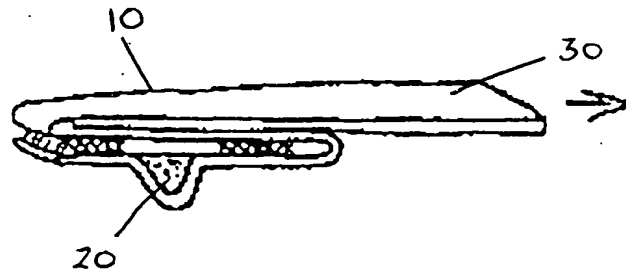
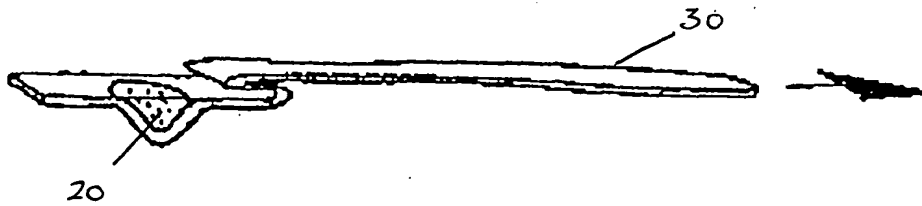
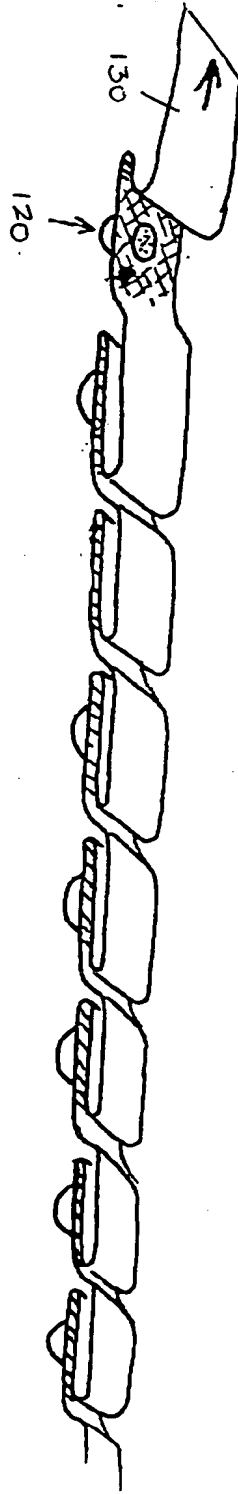


FIGURE 1b



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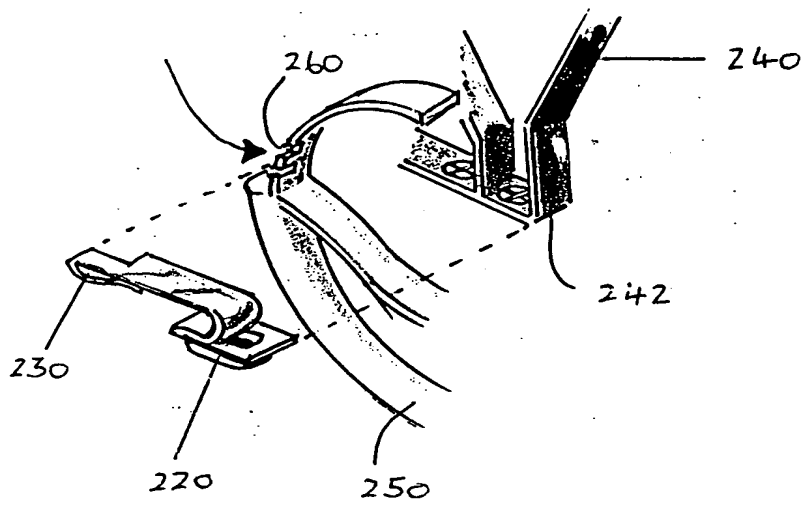
Figure 2



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3a

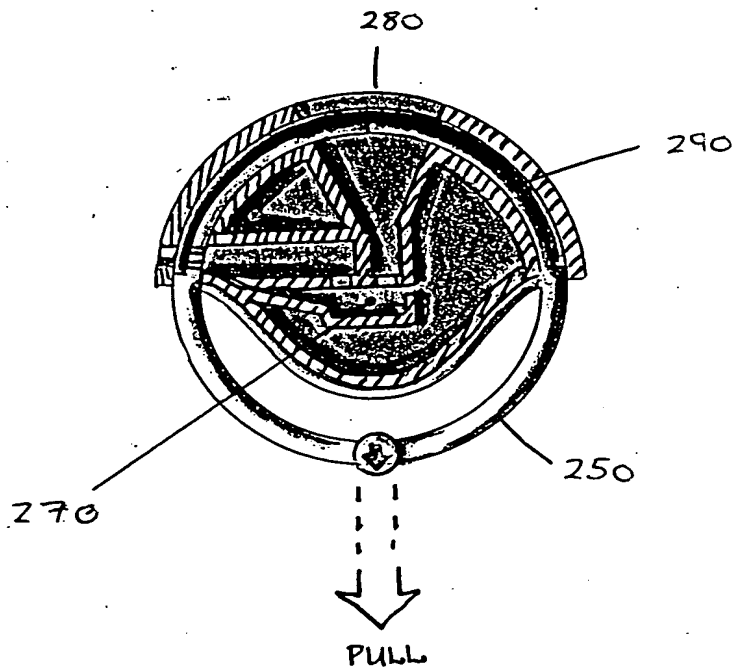
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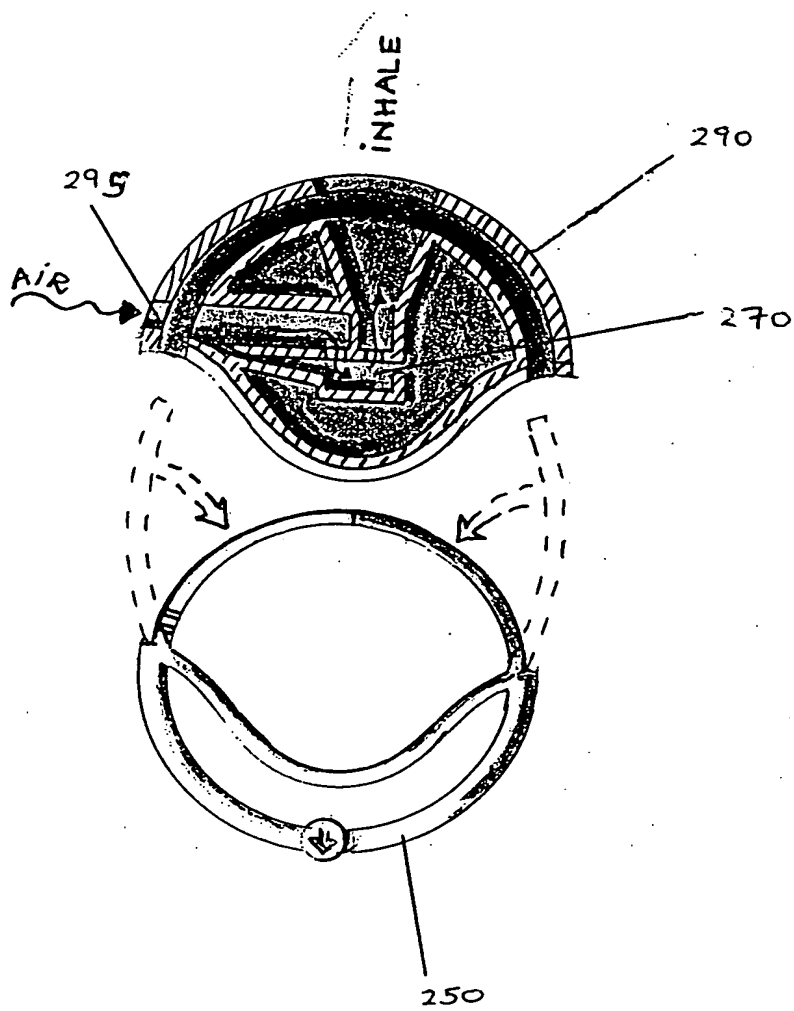
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FIGURE 3c



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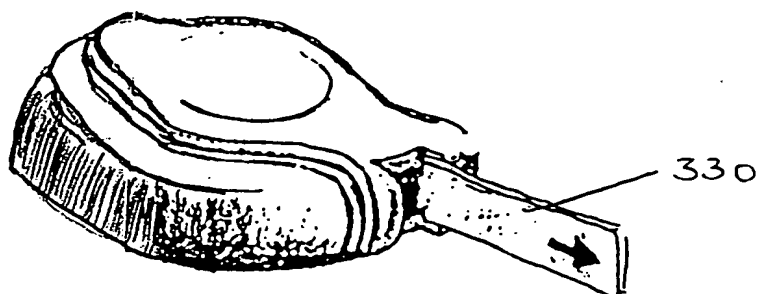
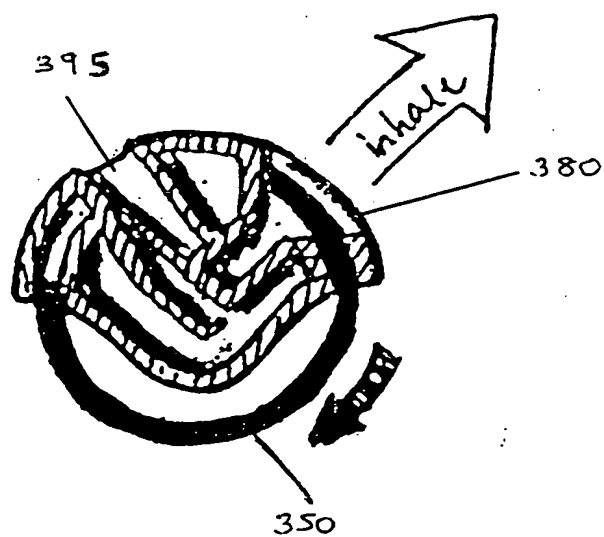


FIGURE 4b



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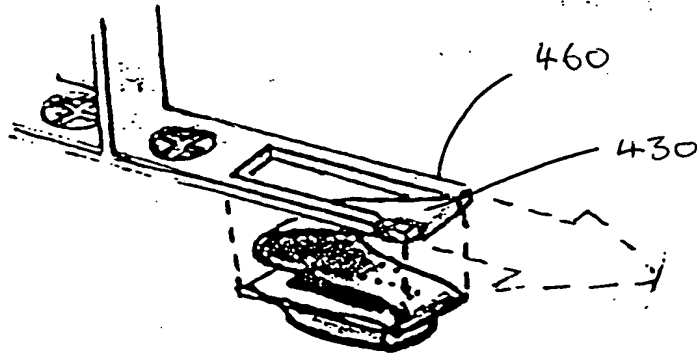


FIGURE 5b

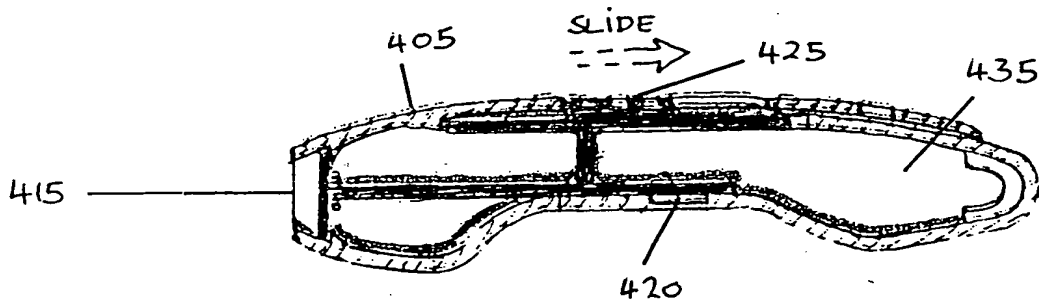
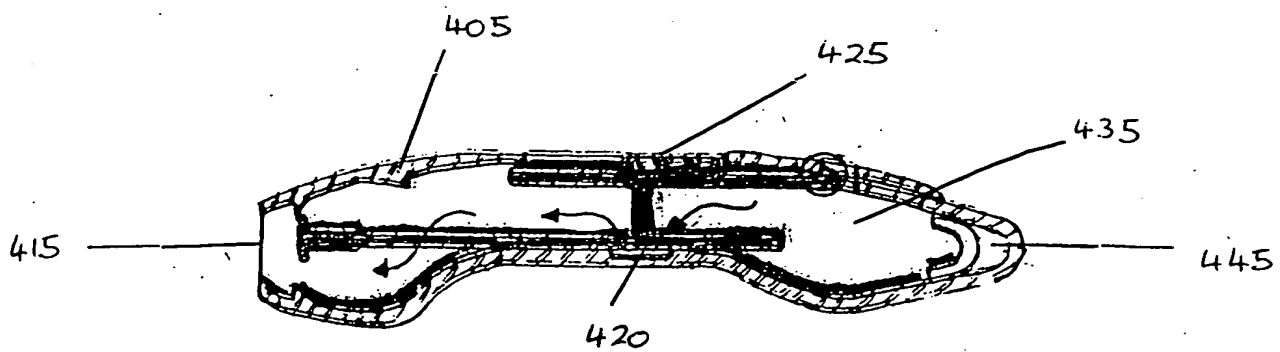


FIGURE 5c



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FIGURE 6a

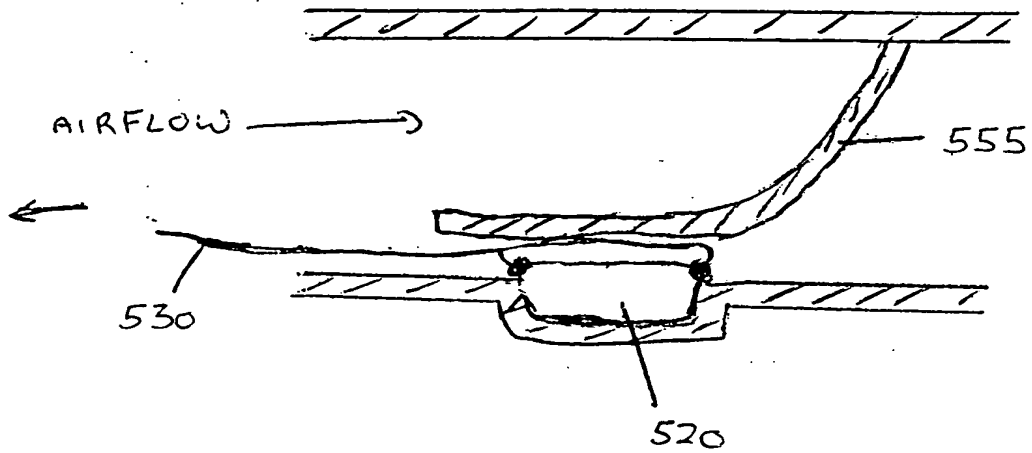
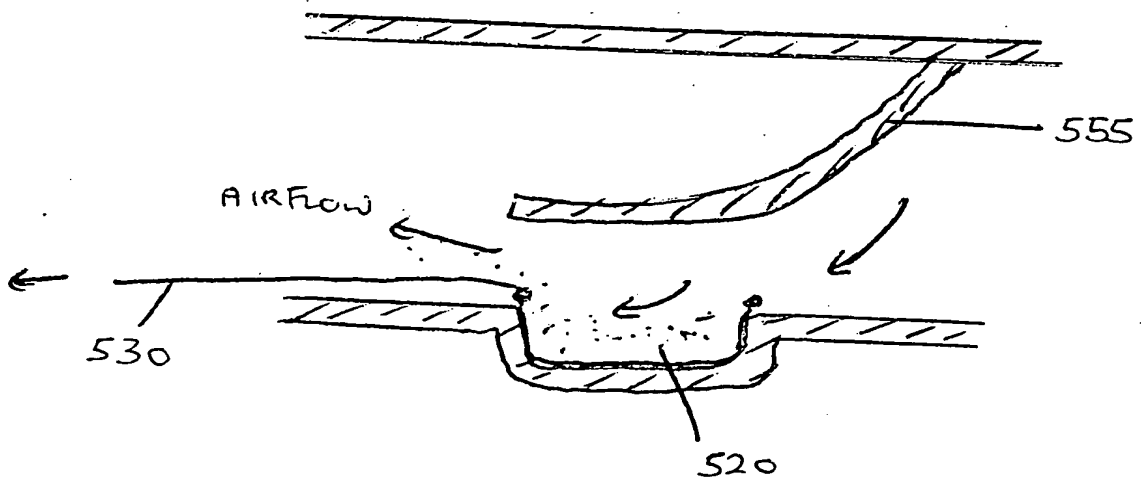


FIGURE 6b



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